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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,883

07/30/2003

Seth A. Foerster

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ALEXANDRIA, VA 22314

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

02/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,883	Applicant(s) FOERSTER ET AL.	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Oath/Declaration

1. This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. Claims 46-51 were added in a preliminary amendment filed on July 30, 2003. This amendment claims subject matter that is not fully disclosed in the current specification. In particular, the current specification is silent with respect to using at least two imaging methods to detect the implanted mass, the implanted mass is detectable for a first time period and does not interfere with the tissue adjacent the implantation site after the first time period, and the use of MRI and ultrasound to detect the mass. Instead, the Applicants rely upon 08/217,246 (now US Pat No 5,526,822) to incorporate by reference the newly claimed elements. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Priority

2. The Applicants claim priority to 08/308,097, filed on September 16, 1994. However, due to the fact that the above-mentioned claimed subject matter is not directly disclosed in the current specification, and the Applicant improperly relies upon the incorporation by reference of 08/217,246 to provide the required support, the current application is being treated as a Continuation-In-Part, with the effective filing date of July, 30, 2003.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 46-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a marker that is bioabsorbable and detectable by an imaging system, does not reasonably provide enablement for a bioabsorbable mass that is detectable by at least two imaging methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 46-51 are not fully enabled by the current specification. In the Response filed on October 15, 2007, the Applicants state the imaging methods are disclosed in 08/217,246, which was incorporated by reference in the current specification. However, the incorporation by reference of 08/217,246, in the current specification, only incorporates the biopsy device and methods of performing the biopsy using imaging techniques. The incorporation by reference does not incorporate the imaging methods used to detect the bioabsorbable mass. "While each element may be individually be discussed neither the specification nor drawings clearly support the claimed embodiment as a whole." "It is not enough that applicant show where each claimed element resides in the earliest filed application but [he] must also provide support for the

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linkage of the claimed elements creating the embodiment.” See *Hyatt v. Dudas*, 492 F.3d 1365, 1370, 83 USPQ2d 1373, 1376 (Fed. Cir. 2007). See also MPEP 2163.04.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 46-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (4,832,686).

Anderson discloses a bioabsorbable means for applying a therapeutic agent to a biopsy site and further disclose a mass of material that is detectable by at least two imaging detection methods when introduced into the cavity site created when the tissue has been removed; the mass remains at the site for at least a first time period after the introduction into the cavity site created when tissue has been removed and does not interfere with imaging during a second time period after the first time period; the mass remains imageable for the first time period and clears from the site during the second time period; and the marker is detectable by at least two of the following imaging methods: MRI, ultrasound, x-ray, mammography or fluoroscopy. See Column 4, lines 8-33; and Column 7, lines 4 and 41-51.

The disclosure of a radiopaque marker inherently discloses the ability to remotely image the marker using x-ray and/or fluoroscopy. Furthermore, the ability of the material

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to degrade in a specified period of time would also inherently disclose the ability to image the site for a first predetermined time and not interfere with imaging during a second time period.

7. Claims 46-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al (6,161,034).

Burbank et al disclose a means for marking a biopsy site and further disclose a mass of material that is detectable by at least two imaging detection methods when introduced into the cavity site created when the tissue has been removed; the mass remains at the site for at least a first time period after the introduction into the cavity site created when tissue has been removed and does not interfere with imaging during a second time period after the first time period; the mass remains imageable for the first time period and clears from the site during the second time period; and the marker is detectable by at least two of the following imaging methods: MRI, ultrasound, x-ray, mammography or fluoroscopy. See Column 4, lines 59-62; and Column 5, lines 47-64.

Response to Arguments

8. Applicant's arguments filed November 19, 2008 have been fully considered but they are not persuasive.

The Applicants argue Anderson fails to disclose a detectable mass of material that remains detectable at the cavity site for a first period of time after introduction into the cavity and does not interfere with imaging of the tissue adjacent the cavity site after the first period of time. The Examiner respectfully disagrees. Anderson discloses a

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bioabsorbable material that can comprise radiopaque markers dispersed throughout the material. Column 6, lines 61-68 to Column 7, lines 1-6, states other components can be incorporated into the composition, including chemotherapeutic agents, antibiotics, hemostatic agents and radiopaque markers. One of ordinary skill in the art, when reading this cited passage, would know the agents are dispersed throughout the composition. Therefore, the addition of radiopaque markers to the composition would also be dispersed throughout the composition, just as the Applicants admitted on Page 10, lines 8-9 in the Remarks.

The Applicants also argue the radiopaque marker elements of Anderson are not bioabsorbable, and therefore would interfere with the imaging of the site after the bioabsorbable matrix has fully dissolved. The Examiner respectfully disagrees. Once the bioabsorbable matrix has fully dissolved, the radiopaque markers, assuming the markers are not bioabsorbable, would migrate from the original implantation site to other parts of the body, thereby preventing any interference of the imaging of the implantation site.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736